AUG 2 9 2003

K032409

510(k) Summary
Vitoss® *Scaffold* Synthetic Cancellous Bone Void Filler

Submitted by	Address	Telephone	Contact Person
Orthovita, Inc.	45 Great Valley Parkway Malvern, PA 19355	(610) 640-1775	Andreina Ide, Sr. Director, Regulatory Affairs

	Subject Device	Predicate Devices
Trade Name →	*Vitoss*® Scaffold Synthetic Cancellous Bone Void Filler	▪ WMT-TCP K022629 ▪ chronOS K013072
Common Name	Resorbable Synthetic Bone Void Filler/Bone Graft Substitute	
Classification Name	Resorbable Calcium Salt Bone Void Filler Device	

Device Description:

Vitoss Scaffold is a porous calcium phosphate resorbable bone void filler for the repair of bony defects. It is an osteoconductive porous implant with a trabecular structure that resembles the multidirectional interconnected porosity of human cancellous bone. Pore diameters in the scaffold range from 1 μm to 1000 μm (1 mm). The implant is provided sterile in block and morsel forms.

Vitoss Scaffold guides the three-dimensional regeneration of bone in the defect site into which it is implanted. When *Vitoss* Scaffold is placed in direct contact with viable host bone, new bone grows in apposition to the calcium phosphate surfaces of the implant. As the implant resorbs, bone and other connective tissues grow into the space previously occupied by the scaffold. Results from animal studies demonstrate that eighty percent of *Vitoss* Scaffold is resorbed within twelve weeks.

Intended Use:

Vitoss Scaffold Synthetic Cancellous Bone Void Filler is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. *Vitoss* Scaffold is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. *Vitoss* Scaffold should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

Vitoss Scaffold is intended to be packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis) and may be combined with autogenous blood

and/or bone marrow. Following placement in the bony void or gap, the calcium phosphate scaffold resorbs and is replaced with bone during the healing process.

Comparison to Predicate:

	Vitoss Scaffold	WMH-TCP	ChronOS
Intended Use	Resorbable Synthetic Bone Void Filler	Resorbable Synthetic Bone Void Filler	Resorbable Synthetic Bone Void Filler
Target Population	Individuals with bony defects resulting from surgery or trauma	Individuals with bony defects resulting from surgery or trauma	Individuals with bony defects resulting from surgery or trauma
Anatomical Locations	Bony voids or gaps of the skeletal system, i.e., the extremities, spine and pelvis	Bony voids or gaps of the skeletal system, i.e., the extremities, spine and pelvis	Bony voids or gaps of the skeletal system, i.e., the extremities, spine and pelvis
Labeling	Labeling contains same intended use as predicate devices	Labeling contains same intended use as *Vitoss Scaffold*	Labeling contains same intended use as *Vitoss Scaffold*
Materials	β-Tricalcium Phosphate $Ca_3(PO_4)_2$ satisfies ASTM F 1088	Tricalcium Phosphate – satisfies ASTM F 1088	β-Tricalcium Phosphate $Ca_3(PO_4)_2$ satisfies ASTM F 1088
Design			
• **Physical Structure**	Trabecular structure similar to cancellous bone	Trabecular structure similar to cancellous bone	Uniform, three-dimensional pore structure
• **Porosity**	Approximately 90%	Reported as "highly porous"	Approximately 60% to 70%
• **Pore Size (range)**	1-1000μm		100-500μm
Performance			
• **Osteoconductivity**	Osteoconductive	Osteoconductive	Osteoconductive
• **Resorption**	Demonstrated as 80% resorbed at twelve weeks	Reported as "resorbable"	Resorption reported to occur between 6 and 12 months.
• **Mechanical Strength**	Does not impart mechanical strength to surgical site	Does not impart mechanical strength to surgical site	Does not impart mechanical strength to surgical site
Sterility	Sterilized by gamma radiation, single use only	Sterilized by gamma radiation, single use only	Sterilized by gamma radiation, single use only
Biocompatibility	Established	Established	Established
Dosage Form(s)	Morsels and Blocks	Granules and Blocks	Granules, Cylinders and Blocks

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Andreina Ide
Sr. Director, Regulatory Affairs
Orthovita, Inc.
45 Great Valley Parkway
Malvern, PA 19355

Re: K032409
Trade Name: Vitoss Scaffold Synthetic Cancellous Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: August 1, 2003
Received: August 4, 2003

Dear Ms. Ide:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K032409

Device Name: *Vitoss® Scaffold* Synthetic Cancellous Bone Void Filler

Indications For Use:

Vitoss Scaffold Synthetic Cancellous Bone Void Filler is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. *Vitoss* Scaffold is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. *Vitoss* Scaffold should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

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PLEASE DO NOT WRITE BELOW THIS LINE
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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milkereit

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032409

Prescription Use _____ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109)